REMARKS/ARGUMENTS

Status of the Claims

Claims 1, 5, 10, 18 and 21-23 are pending with entry of this amendment, claims 2-4, 6-9, 11-17, 19, 20 and 24-54 having been previously cancelled.

Claim 1 is amended herein. This amendment introduces no new matter and support is replete throughout the specification. The amendment is made without prejudice and is not to be construed as abandonment of the previously claimed subject matter or agreement with any objection or rejection of record.

With respect to claim 1, support for Agrobacterium-mediated delivery of nucleic acids is replete throughout the specification. For example, see the specification at paragraphs [0004] and [0010], Examples 1 and 2, and elsewhere.

Also with respect to claim 1, the "core section explant" embodiment has been removed.

Applicants submit that no new matter has been added to the application by way of the above Amendment. Accordingly, entry of the Amendment is respectfully requested. Applicants traverse all rejections, to the extent that they are applied to the amended claims.

The Claims are Free of Mezzetti

Claims 1, 10, 18 and 21-22 were rejected under 35 U.S.C. §102(a) as allegedly anticipated by Mezzetti B. et al. (BMC Biotechnology, Vol. 2, No. 18 (2002)) ("Mezzetti"). To the extent that these rejections are applied to the amended claims, Applicants respectfully traverse.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP §2131, citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Without agreeing with any objection or rejection of record, claim 1 is amended herein for the purpose of facilitating prosecution. As amended, claim 1 is directed to a method of generating a plant comprising transformed plant cells, the method comprising, *inter alia*, transformation of organogenic cells of a leaf base explant. Mezzetti relates to the transformation of sliced meristematic bulk (MB) tissue. At least because the MB tissue of Mezzetti and the leaf

bases of amended claim 1 constitute entirely different tissues, the claims of the present invention are clearly free of Mezzetti. As such, Applicants respectfully request withdrawal of the rejections for alleged anticipation.

Regarding the allegation at page 3 of the Action that "Applicants specification discusses using the same cultivated meristematic tissues as those used in Mezzetti (see Examples 1 and 2 on page 40 paragraph 0138 for example)," Applicants note that paragraph [0138] relates to only *one of multiple steps* of an *example* method described in the present application. The issue for determining anticipation is not whether the cited reference "anticipates" a paragraph in the specification, but rather whether the reference anticipates the *claimed* invention. As such, Applicants do not believe that the subject matter of paragraph [0138] is particularly relevant to whether the claims are anticipated by Mezzetti.

Regarding the Action's assertion that Mezzetti relates to "the same cultivated meristematic tissues," Applicants respectfully disagree. The method of claim 1 – directed to direct organogenic transformation (e.g., the absence of a callus intermediate as claimed) – is readily distinguishable from the indirect method of Mezzetti. It is well known in the art that damaging plant tissue, e.g., by repeated fragmentation and cutting of meristematic bulk tissue as in Mezzetti (see Mezzetti at, e.g., p. 2, right column, second full paragraph), initiates a *wound healing response* that results in *callus formation prior to organogenesis*. In the present invention, by contrast, individual leaves are separated from the shoot without cutting or subsequent sectioning. Upon culture, shoots and shoot buds arise directly from the unwounded surface areas of the leaves, with no formation of a callus intermediate.

Whether or not Mezzetti characterizes their method as regeneration via organogenesis, Mezzetti does not characterize the method disclosed therein as involving direct organogenesis, as expressly claimed in the present invention (via the limitation that at least one plant is generated from the organogenic cells without going through a callus intermediate). While Mezzetti is completely silent on the issue of direct versus indirect organogenesis, one of skill in the art would readily recognize that Mezzetti involves indirect organogenesis upon reading Mezzetti's protocol for generating the MB tissue and culturing the MB tissue post-transformation. The organized cells (i.e., parenchymatous cells with highly vascularized bands, see Figure 2B) that are purportedly transformed in Mezzetti undergo a wound healing process resulting in callus formation, as indicated on p. 2, right column, 3rd full paragraph: transformed MB slices are cultured using very low kanamycin concentrations (25 mg l^{-1}, then 50 mg l^{-1}) for

an extended period of time, clearly to allow individual cells to multiply via the wound healing process (callus formation), before increasing the kanamycin concentration to 75 mg l^{-1}. Eventually, after 7 months of culture, transgenic shoots produced from callus are isolated. Mezzetti is simply inadequate as an anticipatory reference when applied to the claimed method of the present invention involving direct organogenesis. For this reason as well, the rejections for alleged anticipation should be withdrawn.

Applicants also disagree with the assertion at page 3 of the Action that Mezzetti states in the results section that "adventitious shoots are the desired tissue for transformation." Mezzetti does not state that adventitious shoots are the desired tissue for *transformation*. In fact, Mezzetti states that "*meristematic slices*" are the starting material for transformation (see p. 2, right column, second full paragraph, last sentence). There is no evidence in Mezzetti that adventitious shoots are transformed. In Mezzetti, the MB tissue is desirable because of its capacity to produce high numbers of adventitious shoots (see p. 2, right column, second full paragraph), but the *production of shoots from the MB tissue occurs post-transformation*. This is indicated unambiguously in the Methods section of Mezzetti on page 9 under the heading "Genetic transformation": "Slices (1 cm^2, 2 mm thick) obtained from the MB were dipped in the bacterial suspension for 15 min." It is also clear from Figure 3A that the target tissue for transformation is sliced MB tissue prior to the appearance of adventitious shoots (note the smooth surface / absence of shoots). Thus, Mezzetti does not teach adventitious shoots as a desired tissue for transformation. The adventitious shoots to which Mezzetti refers arose from a callus intermediate post-transformation.

The rejection must be withdrawn.

The Claims Are Not Obvious Over Mezzetti

Claims 1, 5, 10, 18 and 21-23 were rejected under 35 U.S.C. §103(a) as allegedly obvious over Mezzetti et al. (BMC Biotechnology, Vol. 2, No. 18 (2002)). To the extent that these rejections are applied to the amended claims, Applicants respectfully traverse.

Three requirements must be met to establish a *prima facie* case of obviousness. First, the prior art reference(s) must teach all of the limitations of the claims. MPEP §2143.03. Second, there must be a common sense rationale to modify the reference or combine the teachings to produce the claimed invention. MPEP §2143.01. Third, a reasonable expectation of success is required. MPEP §2143.02. The teaching or suggestion to combine and the

expectation of success must be both found in the prior art and not based on Applicants' disclosure. MPEP §2143.

For the reasons stated above, the first requirement for establishing a *prima facie* case of obviousness – that the prior art reference(s) teach all of the limitations of the claims – is clearly not met with respect to claim 1 and claims dependent therefrom. Mezzetti – either alone or in combination with the general state of the art at the time the present application was filed – does not teach or suggest culturing a leaf base to produce organogenic cells for transformation via Agrobacterium-mediated delivery. Nor does combining Mezzetti with USPN 6,653,530 cure this deficiency. USPN 6,653,530 relates to the transformation of cells derived from grape plants, but does not teach or suggest, e.g., the organogenic transformation of leaf base explants. For this reason alone, the rejections of the claims based on alleged obviousness should be withdrawn.

The second requirement for establishing a *prima facie* case is not met, as there is simply no common sense rationale for one of skill to modify or combine Mezzetti, which relates (at most) to an indirect organogenic approach for transforming MB tissue sections, to arrive at the direct organogenic transformation of leaf bases as claimed in the instant application. For this reason as well, the rejections should be withdrawn.

The third requirement for establishing obviousness is not met either, at least because Agrobacterium-mediated transformation of leaf base tissue was not taught or suggested in the art, and the success of this approach for transforming leaf base tissue (demonstrated by Applicants at, e.g., Examples 1 and 2 of the specification) would not have been reasonably expected by one of skill in the art at the time the application was filed. Mezzetti relates to Agrobacterium-mediated transformation of MB tissue, but as discussed above, MB tissue and leaf bases represent significantly different targets for transformation. It was well understood in the art at the time of the invention that Agrobacterium-mediated gene delivery is highly sensitive to the type of cells/tissue to be transformed. Given the general unpredictability of Agrobacterium-mediated transformation, and the absence of any evidence in the prior art of the feasibility of this approach as applied to leaf bases, one of skill would not have reasonably expected that Applicants' method for direct organogenic transformation of leaf bases via Agrobacterium-mediated delivery would be successful. Accordingly, none of the three requirements for establishing a prima facie case of obviousness are met, and the rejections should be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the claims are deemed not to be in condition for allowance after consideration of this Response, a telephone interview with the Examiner is hereby requested. Please telephone the undersigned at (510) 337-7871 to schedule an interview.

The Commissioner is hereby authorized to charge any additional fees associated with this paper or during the pendency of this application, or credit any overpayment, to Deposit Account No. 50-0893.

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Respectfully submitted,

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Attachments:

1) A petition to extend the period of response for 1 month;
2) a transmittal sheet;
3) a fee transmittal sheet; and,
4) a receipt indication postcard